DIRECTIONAL GUIDEWIRE

Background of the Invention

Field of the Invention

The present invention relates to a guidewire for use in medical applications and, in particular, to improvements in guidewires used in the placement of intraluminal grafts.

Description of the Related Art

The placement of prosthetic devices, such as stents and grafts, intraluminally and the conduct of operative procedures intraluminally has grown dramatically in recent years. In many of these placements and procedures, it is necessary to initially position a guidewire into a desired part of the lumen of a desired vessel or duct, such as a blood vessel. Once an initial guidewire is in place, a catheter or other tubular device may be positioned over the guidewire and used to convey another guidewire, prosthesis, an endoscope or a surgical instrument into the desired blood vessel or duct.

There are a variety of techniques used to position guidewires intraluminally, however, there are often problems encountered by medical practitioners in achieving the desired placement of a guidewire. One technique that is employed is the use of directional catheters that direct a guidewire passing therethrough in a desired direction. Such a directional catheter may, for example, having a curved end that directs a guidewire passing therethrough and exiting therefrom in a desired direction such as into a branching vessel.

Summary of the Invention

According to a first aspect, the present invention consists in a directable medical guidewire for insertion through a bodily vessel or cavity, the guidewire comprising an elongate resiliently flexible body having a main portion which

will normally assume a straight configuration, and an end portion contiguous with one end of the main portion which will normally assume a curved configuration, the guidewire being characterized in that the curved configuration of the end portion has a first section that normally has a first curvature and a second section that normally has a second different curvature to that of the first section.

For purposes of this specification, the normal configuration of the guidewire according to the present invention is taken to be the configuration adopted by the guidewire on suspension of the guidewire, outside the body, from its end distal the end portion and allowed to hang freely. It is, therefore, expected that the normally straight main portion of the guidewire would extend substantially vertically when the guidewire was suspended from its distal end. Similarly, the normal curvature of any portion of the guidewire is the curvature adopted by the guidewire when suspended as described above. In use, the configuration assumed by portions of the guidewire will vary from their normal configuration due to the resiliently flexible nature of the guidewire as it is passed through the bodily vessel or cavity. The configuration of the guidewire during storage or distribution may also vary from that normally assumed. For example, a guidwire might be coiled and then packaged for distribution and only when removed from the packaging could it assume its normal configuration.

In one embodiment of the present invention, the second portion can be contiguous with an end of the first portion. In a further embodiment, the end portion of the guidewire can have a third section contiguous with an end of the second section that normally has a third different curvature to that of the second section. Instead of having a curvature, the third section can also be normally substantially straight relative to the curvature of the second section. It can also

be envisaged that the end portion could have a fourth or further number of curved or straight sections, depending on how tortuous vessels being treated are.

The first, second and further sections of the end portion can each normally have the curvature of a notional circle, ellipse or the like curved shapes. For example, the first section can have the curvature of a first notional circle having a first radius, and the second portion the curvature of a second notional circle having a second different radius to that of the first circle. In another example, the first portion can have the curvature of a notional circle and the second portion the curvature of a notional ellipse. In a still further example, the first portion can have the curvature of a notional ellipse and the second portion the curvature of a notional circle. In yet a further example, the first section can have the curvature of a first notional ellipse and the second section the curvature of a second notional ellipse.

The first and second section of the end portion of the guidewire can be separated by an intermediate section. The intermediate section can normally assume a straight configuration or can normally assume a curved configuration with a normal curvature different to that normally assumed by the first and second sections. If the intermediate portion normally assumes a curved configuration, the intermediate portion can have the curvature of a notional circle, ellipse or parabola.

In a further embodiment, the end portion has an angle of inflection between the first and second sections such that the first and second curved sections are of opposite curvature. The curvature of the first and second sections can also define notional planes, with the curvature of the second section being in a different notional plane to that of the first section.

In the embodiment of the invention having a normally straight intermediate portion, the normal curvature of the first section is preferably such that the intermediate portion makes an angle of between 10 and 135° to the

longitudinal axis of the normally straight portion. When the guidewire is used in the placement of intraluminal grafts in the aorta and associated iliac arteries, the angle is more preferably between 20 and 45°, and most preferably about 30°. The curvature of the second curved section is also preferably such that the longitudinal axis of the intermediate portion makes and angle between 10 and 135° with a notional straight line extending from the end of the second section or an actual normally straight portion contiguous with the free end of the second section. When the guidewire is used for placement of intraluminal grafts in the aorta and associated iliac arteries, this angle is more preferably between 30 to 60°, most preferably about 45°.

The length of the intermediate portion can be set to suit the application of the guidewire. For use in the placement of intraluminal grafts, the length can be between 1 and 6 cm, more preferably about 3 and 4 cm.

The guidewire can be fabricated from a metal of metal alloy. For example, the guidewire can be fabrication from nitinol alloy. The guidewire can be coated along its length with a suitable material to reduce friction, such as a biocompatible silicone based lubricant.

In a second aspect, the present invention comprises a kit having a guiding catheter that has disposed therein a directable medical guidewire as defined herein.

In a still further aspect, the present invention comprises a method for positioning a guidewire as defined herein within a bodily vessel that is branching off a first vessel, comprising the steps of introducing a kit according to the second aspect of the present invention into the first vessel.

Briefly stated, there is provided that novel and enhanced guidewire iterations are provided with curvilinear end portions and methods of used of the same for endovascular grafting; for example, are taught.

According to a feature of the present invention there is provided a directable medical guidewire having two ends and an outer surface for insertion through a lumen comprising: an elongate resiliently flexible body having a main portion biased into a first configuration; and, an end portion contiguous with one end of the main portion defined by a curved configuration having a first section with a first curvature and a second section having a second different curvature to that of the first section.

According to another feature of the present invention there is provided a method of emplacing the guidewire defined by claim 1, wherein said guidewire is adapted to be suspended outside of a body having a lumen, and whereby the end distal said end portion hangs freely.

In yet another feature of the present invention there is provided a method of using the guidewire defined by claim 1, including the steps of varying the configuration of said guidewire during storage by coiling said guidewire into a spring biased state, packing said guidewire; removing said guidewire; and reconfiguring an unbiased orientation in of said guidewire in said lumen.

In yet another feature of the present application there is provided a guidewire defined by claim 1, further comprising at least one of a metal and alloy selected from the group consisting of nitinol, nickel, titanium, stainless steel, elgiloy, palladium and the like super-elastic or flexible substantially metallic or magnetic combinations.

In yet still another feature of the present invention there is provided a guidewire defined by claim 1, wherein said outer surface is coated by at least one biocompatible substance selected from the group consisting of PET, PTFE, silicone based lubricants and the like plastic-based materials.

A kit which comprises a guiding catheter having a directable medical guidewire disposed therein; a first means for emplacing the guidewire; a means

for adjusting the emplaced guidewire; and a second means for emplacing the guidewire.

Brief Description of the Drawings

Hereinafter by way of example only, preferred embodiments of the present invention are now described with reference to the accompanying drawings, in which:

FIG. 1 is a simplified diagrammatic representation of a ventral view of a patient having an aortic aneurysm bridged by a trouser graft;

FIGS. 2a-i show the stages of carrying out a method of intraluminally placing a trouser graft into a patient, which uses the invention, defined herein:

FIG. 3a-d are side elevational views of different embodiments of a guidewire according to the present invention;

FIG. 4 is a vertical sectional view of one embodiment of a possible bifurcated graft mounted over a delivery catheter for use in the method depicted in Figs. 2a-I; and

FIG. 5 is a vertical sectional view of one embodiment of a tubular graft mounted over a delivery catheter for use in the method depicted in Figs. 2a-i.

Detailed Description Of the Invention

The present invention can be used in any surgical procedure where it is necessary to direct a guidewire into a bodily vessel whether it be for the placement of an intraluminal graft of another surgical procedure. Examples of vessels in which it can be necessary to direct a guidewire include the renal, vesical and iliac arteries.

The present invention is hereinafter described with reference to the example of the placement of an intraluminal graft into a patient to achieve at least one of the bridging and occlusion of an aortic aneurysm. Those having a

modicum of skill likewise are cognizant of related procedures and locations, including, but not limited to thoracic situses and the like.

As seen in Figure 1, the aorta 10 branches into the right and left iliac arteries 12.13. The aortic aneurysm 14 is located between the renal arteries 15.16 and extend downs the left iliac artery 13. One means of bridging the aneurysm 14 is to use a trouser graft 17, which is provided with a bifurcation to form a pair of short tubular extensions 19, 19a that are connected to tubular grafts 17a, 17b that extend down the iliac arteries 12, 13 respectively. One such trouser graft is described in Australian Patent Specification No AU-A-78035/94, the description of which is incorporated herein by reference.

The method for positioning an intraluminal graft will now be described with reference to Figures2a-i. In carrying out the method an incision or puncture is made to expose the one of the femoral arteries (eg: ipsilateral), which flows from the corresponding iliac artery, and using the Seldinger needle technique, a 0.035' diameter floppy tipped flexible guidewire is inserted into and through the femoral artery and then the iliac artery 12 into the aorta 10 such that it traverses the aneurysm 14. An 8 French haemostatic sheath is then introduced over the wire to control bleeding. An angiographic catheter is then introduced to allow an angiogram to be taken of the patient to show the position of the renal arteries 15,16 and other relevant anatomical structures in the patient.

An Amplatz extra stiff AES guidewire 23 (0.035' diameter) is then passed through the angiographic catheter into the aorta 10. After withdrawal of the angiographic catheter, the stiff guidewire 23 is left in situ. A sheath 21, preferable of 24 French, and a dilator are then introduced into the aorta 10 over the stiff guidewire 23 (see Figure 2a). A balloon catheter 24 is then introduced into the sheath 21.

As seen in Figure 4, the balloon catheter 24 is a delivery catheter which is pre-packaged with a bifurcated graft 17, having a bifurcation point 17c, and

ipsilateral extension 19, a contralateral extension 19a, and a thin catheter 25 containing a guidewire 26 extending in a first direction up through the ipsilateral tubular graft extension 19 and then in a second different direction into the contralateral extension 19a.

When the balloon catheter 24 is positioned within the aorta 10 correctly, the sheath 21 is partially withdrawn to free the graft so that the balloon 20 may be inflated (see Figure 2b). The inflation of the balloon 20 of catheter 24 expands the upstream end of the first graft 17 and causes it to engage its upstream end against the aorta wall above the aneurysm but downstream of the renal arteries 15,16. The first graft 17 is of such a length that the short tubular extensions 19, 19a are disposed wholly within the aorta 10. The balloon 20 is then deflated but the balloon catheter is left in place for the time being (see Figure 2c). Deflation of the balloon 20 allows blood to flow down the graft 17 distending the first graft 17 and the tubular extensions 19, 19a.

The thin catheter 25 is preferably 3 French and resiliently flexible guidewire 26 is preferably comprised of a nitinol alloy core with a hydrophilic coating. Once the first graft 17 is in place, it is necessary to extend the guidewire 26, which is depicted in its normal configuration in Fig. 3a outside the body, has a straight main portion 50 and an end portion 51 having a curved configuration. The end portion 51 is comprised of a first curved section 52 and a second curved section 53 separated by a relatively short linear intermediate portion 54. The curvature of the first curved portion 53 is preferably such that the intermediate portion 54 makes an angle of about 30° to the longitudinal axis 55 of the straight main portion 50. For other applications of the guidewire or, where required for the present illustrative application, the curvature of the first curved section can, however, be varied such that the angle lies in the range 10 to 135°. The curvature of the second curved section 53 is such that the longitudinal axis 56 of the normally straight intermediate portion is at an angle of about 45° to a notional

straight line 57 (depicted in phantom) extending from the end of the second curved section 53. As with the first curved section, the curvature of the second curved section can be varied such that the angle lies somewhere in the range of 10 to 135°. The length of the intermediate portion 54 in the depicted embodiment is 3 cm. The double curvature of the guidewire 26 allows the guidewire 26 to be guided through the contralateral iliac artery and appropriately enter the contralateral femoral artery 13a (see Fig.2c).

Once the guidewire 26 is correctly placed in the contralateral femoral artery 13a, which is cross-clamped, and an arteriotomy affected. If the guidewire 26 has been guided fully into the contralateral femoral artery 13a, the guidewire 26 is simply recovered by drawing the guidewire through the incision or puncture made in the artery 13a. If the guidewire 26 has not been guided fully along the femoral artery 13a, a snare or similar device can be introduced through the contralateral femoral artery 13a to grab the guidewire 26 and draw it back to the puncture or incision site for retrieval. Once the guidewire 26 is retrieved, the thin catheter 25 is then withdrawn via the ipsilateral side and another catheter 27 is then fed through the contalateral femoral artery 13a over the guidewire 26 until it is within the first graft 17 and reaches at least the top of the contralateral tubular extension19a. The guidewire 26 is then withdrawn and a stiffer guidewire 30 is inserted through the contralateral femoral artery 13a into the catheter 27. The catheter 27 is then removed and a catheter sheath 21a, and a dilator are introduced over the siff guidewire 30 (see Figure 2e).

Prior to extending the guidewire 26 into the contralateral iliac and femoral arteries, a catheter sheath (similar to catheter sheath 21) can be extended upstream through the contralateral femoral and iliac arteries to reduce any tortuosity that may be present in these arteries and so facilitate guiding of the guidewire 26 therethough.

A second balloon catheter 24a, such as is depicted in Fig.5, on which is packaged a second tubular graft 17b is then introduced through catheter sheath 21a until its upper end is well within the contralateral tubular extension 19a at its upper end and with the iliac artery 13 at its lower end. The balloon 20a on the catheter 24a is inflated such that the upper end of graft 17b is frictionally engaged with the contralateral tubular extension 19a (see Figure 2f). The inflation of the balloon 20a on the catheter 24a supports the graft 17 during the withdrawal of the first balloon catheter 24 through the ipsilateral iliac artery 12. The balloon 20 is then deflated and the catheter 24a is maintained in place to provide continued support for the grafts 17, 17b in the aorta 10 while the third graft is positioned.

The catheter sheath 21a is then removed (see Figures 2f and 2g) and a third balloon catheter, on which is packaged a tubular graft 17a, (the third balloon catheter can be identical to that depicted in Fig.5) is introduced into the sheath 21 on guidewire 23. It is advanced until its upstream end is within the ipsilateral extension 19 and, following partial withdrawal of the sheath 21, is then deployed. The third graft 17a positioned on the third balloon catheter is thus urged at its upstream end into contact with the ipsilateral extension 19 and its downstream end into contact with the right iliac artery 12 (see Figure 2h).

The stiff guidwires 23 and 30 are now withdrawn and the contralateral incision or puncture sutured. A second angiographic examination now takes place and if the grafts 17, 17a and 17b are correctly placed and functioning, the haemostatic sheath 21 is withdrawn and the right femoral incision sutured. The result is a functioning trouser graft bridging an aneurysm as is depicted in Fig. 2i.

The operation may be carried out using a general anesthetic, an epidural anaesthetic, an epidural anesthetic, or in suitable cases, using only a local anesthetic.

Alternative guidewires to that depicted as 26 in Fig. 3a are depicted in Figs. 3b-c. Figure 3b depicts a resiliently flexible guidewire body 60 having a

normally straight main portion 50 and an end portion 51. The end portion 51 is comprised of a first curved section 61 having the curvature of a first circle, a second curved section 62 having the curvature of a different circle, and a curved intermediate portion 63 having the curvature of an ellipse. Fig. 3c depicts a resiliently flexible guidewire 70 having a normally straight mail portion 50 and a curved end portion 51, with the curved end portion 51 comprised of a first curved section 71 having the curvature of a notional circle and a second curved section 72 contiguous with the end of the first curved section 71 and having the curvature of a different notional circle. Guidewires having end portions with still further curved configurations can also be envisaged.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.